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Express Mail No.: EL 451 599553US

Date Mailed: February 19, 2003

Serial Number: 10/052,417

Filing Date: 01/17/02

Inventors: Gelfand *et al*

For: *Thermostable DNA Polymerases Incorporating Nucleoside Triphosphates Labelled With Fluorescein Family Dyes*

**Enclosures:**

- 1) Information Disclosure Statement;
- 2) List of Cited References by applicant;
- 3) Explanation of Relevance Under 37 § 1.98(3)(i); and
- 3) Postcard.

File No. 001803-329-999

Sender: RRP/DCP/vcs.



02-24-03

1655

Express Mail No.: EL 451 599 553 US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Gelfand *et al.*

Confirmation No: 4095

Serial No.: 10/052,417

Group Art Unit: 1655

Filed: January 17, 2002

Examiner: Souaya, J.

For: THERMOSTABLE DNA  
POLYMERASES INCORPORATING  
NUCLEOSIDE TRIPHOSPHATES LABELED  
WITH FLUORESCCEIN FAMILY DYES

Attorney Docket No.: 1803-329-999

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FEB 25 2003  
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**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.

1b. A legible copy of:

☒ Each U.S. patent application publication and U.S. and foreign patent;

☒ Each publication or that portion which caused it to be listed on the PTO-1449;

☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;

☐ all other information or portion which caused it to be listed on the PTO-1449.

1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.

- 1d. ☒ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
  - ☒ Before the mailing of the first Office action on the merits;
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

*(Check either Item 3a or 3b)*

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
  - ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

*(Item 3b to be checked if any reference known for more than 3 months)*

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement *(applicable if Item 3a or Item 4 is checked)*

*(Check either Item 5a or 5b)*

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

- 5b. ☐ In accordance with 37 C.F.R. §1.97(e)(2), it is certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was known by any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

6. ☒ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

*(Check appropriate Items 6a, 6b and/or 6c)*

- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.

- 6b. ☒ Copies of publications that were cited in prior application Serial No. 09/146,631, filed on 9/03/98, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).

- 6c. ☒ Copies of the publications listed on Form PTO-1449 that were not previously cited in prior application Serial No. 09/146,631, filed on 9/03/98, are provided herewith.

7. ☐ This is a Supplemental Information Disclosure Statement. *(Check either Item 7a or 7b)*

- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on \_\_\_\_\_. A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on \_\_\_\_\_.

- 7b. ☐ This Supplemental Information Disclosure Statement is timely filed within one (1) month of a PTO Notice under 37 C.F.R. §1.97(i).

8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:

*( Check Item 8a, 8b, or 8c)*

- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.


- 8b. ☐ set forth in the application.

- 8c. ☐ enclosed as an attachment hereto.

9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: February 19, 2003

  
42,983  
Rahul Pathak (Reg. No.)  
For: Nikolaos C. George (Reg No. 39,201)  
**PENNIE & EDMONDS** LLP  
3300 Hillview Avenue  
Palo Alto, California 94304  
(650) 493 - 4935



FEB 19 2003

## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.

1803-329-999

APPLICATION NO.

10/052,417

APPLICANT

Gelfand et al.

FILING DATE

1/17/02

GROUP

1655

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,889,818	12/26/89	Gelfand et al.			
	5,446,591	11/14/95	Abramson et al.			
	5,545,548	8/13/96	Senter et al.			
	5,614,365	3/25/97	Tabor et al.			
	6,083,686	7/04/00	Sullivan			

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## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
					YES	NO
EP 0 655 506	11/24/94	EPO				
EP 0 823 479	7/31/97	EPO				
HU 210959	11/28/91	Hungary				
HU 62334	4/28/93	Hungary				
WO 98/40496	3/12/98	PCT				

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	Beese <i>et al.</i> , "Crystal structures of the Klenow Fragment of DNA polymerase I complexed with Deoxynucleoside Triphosphate and Pyrophosphate", <i>Biochemistry</i> (1993) 32:14095-101.
	Delarue <i>et al.</i> , "An attempt to unify the structure of polymerases", <i>Protein Engineering</i> (1990) 3:467-467
	Donlin <i>et al.</i> , "Mutants affecting nucleotide recognition by T7 DNA polymerase", <i>Biochemistry</i> (1994) 33:14908-14917
	Ito <i>et al.</i> , "Compilation and alignment of DNA polymerase sequences", <i>Nucleic Acids Research</i> (1991) 19:4045-4057
	Lee <i>et al.</i> , "DNA sequencing with dye labeled terminators and T7 DNA polymerase: effect of dyes and dNTPs on incorporation of dye-terminators and probability analysis of termination fragments", <i>Nucleic Acids Research</i> (1992) 20:2471-2483
	Lomize <i>et al.</i> , "Prediction of protein structure: the problem of fold multiplicity", <i>Proteins: structure, function, and genetics</i> , (1999) Suppl 3: 199-203
	Polesky <i>et al.</i> , "Side chains involved in catalysis of the polymerase reaction of DNA polymerase I from <i>Escherichia coli</i> ", <i>The Journal of Biological Chemistry</i> (1992) 267:8417-8428
	Reeve <i>et al.</i> , "A Novel Thermostable Polymerase for DNA Sequencing", <i>Nature</i> (1995) 376:796-797.
	Sanger <i>et al.</i> , "DNA sequencing with chain-terminating inhibition", <i>PNAS</i> (1977) 74:5463-5467
	Voss <i>et al.</i> , "Automated Cycle Sequencing with Taq polymerase: Protocols For Internal Labeling, Dye Primer and "Doublex" Simultaneous Sequencing", <i>Biotechniques</i> (1997) 23:312-318.

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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Explanation of Relevance Under 37 C.F.R. § 1.98(3)(i)

Assistant Commissioner for Patents  
Washington, D.C. 20231


Sir:

The List of References Cited By Applicant (*PTO-1449*) attached to this Information Disclosure Statement in connection with the above-referenced application contains Hungarian Patent Publications HU 62334 and HU 210 959, which are not in the English language. In satisfaction of Applicants' duty to provide an explanation of the relevance of these foreign language documents pursuant to 37 C.F.R. § 1.98 (3)(i), Applicants respectfully submit corresponding U.S. Patent Nos. 5,545,548 ("the '548 patent") and 6,083,686 ("the '686 patent"). HU 210 959 and the '548 patent each claim priority to the same U.S. patent application, while HU 62334 claims priority to the '686 patent.

Applicants respectfully request that the '548 and '686 patents be considered for explanation as to the relevance of the two Hungarian patent publications discussed above. Should the P.T.O. desire a further explanation of the relevance of these patent publications, Applicants respectfully request that the Office specifically indicate what explanation is expected.

Respectfully submitted,

Date: February 19, 2003

  
42,983  
Rahul Pathak (Reg. No.)  
For: Nikolaos C. George (Reg No. 39,201)  
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